Maryland
DEPARTMENT OF HEALTH

Aveed (testosterone undecanoate)

Aveed (testosterone undecanoate) is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, including:

- Primary hypogonadism (congenital or acquired).
- Hypogonadotropic hypogonadism (congenital or acquired).

Aveed should only be used in patients who require testosterone replacement therapy and when the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis.

I. Criteria for Initial Approval

Aveed will be considered for coverage when **all** of the criteria below are met, confirmed with supporting medical documentation.

- Patient is male and 18 years or older.
- Patient has a diagnosis of congenital/acquired primary hypogonadism or congenital/acquired hypogonadotropic hypogonadism.
    - Primary hypogonadism (congenital or acquired) (for example, bilateral torsion, cryptorchidism, chemotherapy, Klinefelter Syndrome, orchitis, orchiectomy, toxic damage from alcohol or heavy metals, Vanishing Testis Syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]); OR
    - Hypogonadotropic hypogonadism (also called secondary hypogonadism) (congenital or acquired) (e.g., idiopathic gonadotropic or luteinizing hormone-releasing hormone (LHRH) deficiency, pituitary- hypothalamic injury).

- Patient presents with symptoms associated with hypogonadism, such as, but not limited to, at least one of the following:
    - Reduced sexual desire (libido) and activity.
    - Decreased spontaneous erections.
    - Breast discomfort/gynecomastia.
    - Loss of body (axillary and pubic) hair, reduced need for shaving.
    - Very small (especially less than 5 mL) or shrinking testes.
    - Inability to father children or low/zero sperm count.
    - Height loss, low trauma fracture, low bone mineral density.

    - Hot flushes, sweats.
    - Other less specific signs and symptoms including: decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, or diminished physical or work performance.
- Prior to starting testosterone therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level is provided to confirm a low testosterone serum level indicating one of the following:
    - Level is below normal, per the lab reference range for stated age. For example:
        - Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; OR
        - Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL.
- Provider and facility must be enrolled in Aveed® REMS Program.
- Documentation of failure of prior therapy (trial/failure unless contraindicated) and, at minimum, two other testosterone formulations.
- Must not have a contraindication for use, such as current or past history of breast or prostate cancer.

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy (in **Section I.**) must be met; **AND** the provider must attest to a positive clinical response.

Patient met all diagnostic criteria for initial therapy; AND

- Has obtained clinical benefits as noted by symptom improvement.

III. Dosing/Administration

Aveed must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- 3 mL (750 mg) of Aveed injected intramuscularly, followed by 3 mL (750 mg) injected after 4 weeks, then 3 mL (750 mg) injected every 10 weeks thereafter.

IV. Length of Authorization for Therapy

Aveed will be authorized for 12 months when criteria for initial approval are met. Continuing therapy with Aveed will be authorized for 12 months.

V. Billing Code/Information

J3145 Aveed Injection, testosterone undecanoate, 1 mg; 1 billable unit = 1 mg

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 2/23/2021
Last Reviewed Date: 2/23/2021